

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ORIGINAL

THE PROCTER & GAMBLE CO.,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	Civil Action No. 04-940 (JJF)
	)	
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

DEFENDANT'S INITIAL DISCLOSURES PURSUANT  
TO RULE 26(a)(1), FED. R. CIV. P.

In accordance with Rule 26(a)(1), defendant Teva Pharmaceuticals USA, Inc. ("Teva") provides the following initial disclosures.

A. The following are likely to have discoverable information relevant to the pharmaceutical composition that is the subject of Teva's Abbreviated New Drug Application ("ANDA") No. 77-132:

Deborah Jaskot  
Teva Pharmaceuticals USA  
1090 Horsham Road  
North Wales, PA 19454-1090

B. The following are documents relevant to the disputed facts alleged with particularity in the pleadings. Copies are located at the offices of Kenyon & Kenyon, One Broadway, New York, NY 10004, and can be made available at a mutually agreeable time.

- (1) ANDA No. 77-132, relevant portions of which are located at Teva's facility in North Wales, PA.

- (2) Prosecution histories for U.S. Patent Nos. 5,583,122, 5,994,329, 6,432,932, and 6,465,443, including Interference 102,399.
- (3) U.S. Patent Nos. 5,730,715, 5,869,471, 4,761,406, 4,416,877, and 3,400,150.
- (4) Tang *et al.*, *Restoring and Maintaining Bone in Osteopenic Female Rat Skeleton: I. Changes in Bone Mass and Structure*, J. Bone Min. Res. 7(9)L: 1093-104 (1992).
- (5) Jee *et al.*, *Extra Cancellous Bone Induced by Combined Prostaglandin E<sub>2</sub> and Risedronate Administration Is Maintained After Their Withdrawal in Older Female Rats*, J. Bone Min. Res. 10(6): 963-70 (1995).
- (6) Ma *et al.*, *Partial Maintenance of Extra Cancellous Bone Mass by Antiresponsive Agents After Discontinuation of Human Parathyroid Hormone (1-38) in Right Hindlimb Immobilized Rats*, J. Bone Min. Res. 10(6): 963-70 (1995).
- (7) Sedor *et al.*, *The Biphosphonate Alendronate (MK-217) Inhibits Bone Loss Due to Ovariectomy in Rats*, J. Bone Min. Res. 6, 339-46 (1991).
- (8) Francis, *Oral Biphosphonates in the treatment of Osteoporosis: A Review*, 56(9) Curr. Ther. Res. 831-51 (1995).
- (9) Reid *et al.*, *Biochemical and Radiologic Improvement in Paget's Disease of Bone Treated with Alendronate: A Randomized, Placebo-Controlled Trial*, Am. J. Med. 101: 341-48 (Oct. 1996).
- (10) Khan *et al.*, *Alendronate in the Treatment of Paget's Disease of Bone*, Bone 20(3): 263-271 (1997).
- (11) *Lunar News*, July 1996, "Update: Biphosphonate," p. 23.
- (12) *Lunar News*, April 1996, "Update: Biphosphonate," p. 31.

- (13) Reddy, *Alendronate Treatment of Naturally-Occurring Periodontitis in Beagle Dogs*, J. Periodontology, 66: 211-17 (1995).
- (14) Blank *et al.*, *Nonclinical Model for Assessing Gastric Effects of Biphosphonates*, Dig. Dis. Sci. 42(2): 281-288 (Feb. 1997).
- (15) Chestnut *et al.*, *Alendronate Treatment of the Postmenopausal Osteoporotic Woman: Effect of Multiple Doses on Bone Mass and Bone Remodeling*, Am. J. Med. 99: 144-152 (Aug. 1995).
- (16) Mortensen, *et al.*, *Risedronate Increases Bone Mass in an Early Postmenopausal Population: Two Years of Treatment Plus One Year of Follow-up*, J. Clin. Endo. Met. 82(2): 396-402 (1998).
- (17) March 1996 Merck "Dear Doctor" letter
- (18) PCT Application WO95/30421
- (19) The Federal Circuit Decision in *Merck v. Teva*, Appeal 04-1005, dated January 28, 2005.
- (20) Documents and materials produced in the litigation *Merck v. Teva*, 01-CV-0048 JJF in the District of Delaware.
- C. Not applicable.
- D. Not applicable.

YOUNG, CONAWAY, STARGATT & TAYLOR

March 7, 2005

By Josy W. Ingersoll (by AP 3880)  
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**CERTIFICATE OF SERVICE**


I, Adam W. Poff, hereby certify that I caused copies of the foregoing document to be served on March 8, 2005, upon the following counsel of record in the manner indicated:

**BY HAND DELIVERY**

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A handwritten signature in black ink, appearing to be 'AP', is positioned above a horizontal line.

Adam W. Poff (#3990)